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April 6, 1992

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Federal Communications Commission
Office of the Secretary

Ms. Donna R. Searcy
Secretary
Federal Communications Commission
1919 M Street, NW, Room 222
Washington, DC 20554

Re: RM No. 7903

Dear Ms. Searcy:

Enclosed please find the original and nine copies of the Reply Comments of the National Electrical Manufacturers Association in the above-referenced proceeding.

Any questions concerning this matter should be directed to the undersigned.

Yours very sincerely,

Lawrence J. Movshin

LJM/att
Enclosures
cc: Dr. Thomas P. Stanley
Mr. Robert Cutts
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Before the

FEDERAL COMMUNICATIONS COMMISSION

Washington, D.C. 20054

In the Matter of	)	
	)	
Amendment of §18.121 of the	)	
Commission's Rules to Exempt	)	**RM No. 7903**
Non-consumer Magnetic	)	
Resonance Diagnostic Systems	)	
From The Technical Standards	)	
and the Reporting Requirements	)	
of the Commission's Rules	)	

TO: The Commission

REPLY COMMENTS OF THE
NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

The Magnetic Resonance Section of the National Electrical Manufacturers Association ("NEMA"), by its attorneys and pursuant to Commission Rule § 1.405(b) hereby replies to the comments filed on the above-referenced Rulemaking Petition. All of the commenters supported the initiation of the requested rulemaking proceeding. For the reasons stated in the Petition, as amplified in response to the comments, NEMA urges prompt action on its Petition, and the expeditious initiation of rulemaking proceedings designed to exempt non-consumer magnetic resonance diagnostic systems from the technical standards and the reporting requirements of the Commission's rules.

As NEMA established in the Petition, the Commission has consistently recognized that the primary intent of its Part 18 regulations is the protection of licensed communications services and facilities. Where it has been demonstrated that, by reason of the design or nature of anticipated use, the imposition of specific emission limits and compliance testing requirements is unnecessary to achieve this objective, the Commission has consistently exempted classes or types of products from such requirements. In such cases, the agency has instead relied on a generic non-interference requirement to meet its objectives.

NEMA has made such a demonstration as to Magnetic Resonance (MR) diagnostic systems, and thus an exemption is warranted for MR diagnostic devices. MR diagnostic systems are non-consumer devices that are primarily located in the RF-noise controlled environment of hospitals and medical clinics. In such environments, potential emissions from the system are not likely to create harmful interference to the operation of authorized telecommunications services. As a general matter, receivers associated with such services are not likely to be found in the vicinity of MR devices. Furthermore, hospitals and clinics are typically constructed of reinforced concrete and steel according to building codes, which provide an additional, significant level of shielding from MR diagnostic and other medical devices to authorized telecommunication services. NEMA also demonstrated that absent an exemption, by virtue of the size, weight, shielding and power requirements of MR diagnostic systems, the

burden of compliance with the technical and administrative requirements of the rules can be enormous.

In the face of this burden, NEMA demonstrated that there would be little public benefit to maintaining these requirements on MR systems. There have not been any complaints of objectionable interference lodged against an MR system. Given the design of such systems, with their highly integrated shielding techniques, it is highly unlikely that such objectionable interference would occur. Indeed, the MR system is far more likely to be susceptible to, rather than the creator of, such interference.

All three of the commenting parties supported NEMA's position. Philips Medical Systems, a NEMA member, strongly supported the proposed rulemaking, arguing that the requested exemption would be important to help in the control of the increasing cost of medical care, thereby increasing the availability of this non-invasive diagnostic modality to the general public. As Philips emphasized, over 1,000 MR systems are in use by the medical profession without causing interference or inconvenience to radio frequency communications. GE Medical Systems, another NEMA member, also supported the issuance of the requested rulemaking. As GE noted, "in view of the extreme sensitivity of [MR systems] and the measures taken to shield them from interference due to other sources of RF signals, it is considered highly unlikely that these systems will be a source of interference to communications."

Hewlett Packard Company Medical Products Group ("HP"), also a NEMA member, generally supported the NEMA initiative as well. HP favored the potential that adoption of the requested relief could eliminate the burden of unnecessary regulation and reduce the regulatory costs imposed on vital medical technologies such as magnetic resonance imaging devices. But HP also urged the Commission to move cautiously in adopting the proposed relief; HP, at least, is not as sanguine as other NEMA members with the assumption that MR diagnostic systems will not create interference to the electrocardiogram (ECG) telemetry systems that HP markets into the hospital environment. In particular, HP suggests that before the Commission adopts the requested exemption, MR diagnostic systems must be studied to assure that they are not creating potentially objectionable levels of interference to ECG devices operating in the offset or splinter frequencies in the 450-470 MHz band.

As a threshold matter, NEMA does not oppose the further study of the hospital environment in the context of an expeditiously initiated rulemaking proceeding. Indeed, NEMA would welcome the Commission's undertaking of analyses like those made in deciding to grant a similar exemption from most Part 18 requirements for non-consumer ultrasonic ISM equipment. NEMA is certain that such studies would fully support the analyses and assertions of its members that MR devices do not create objectionable interference to other medical devices in the medical environment. The key is to get the rulemaking started. Once initiated, the types of studies and analyses necessary

empirically to demonstrate the validity of the assumptions underlying the request for relief can be appropriately focused.

NEMA does not, however, agree with HP's specific assertion concerning the potential for harmful interference from MR diagnostic systems operating in the 450-470 MHz band, and clearly disputes the suggestion that MR devices may have been responsible for intermittent episodes of interference to ECG monitoring systems. First, it should be noted that the operating frequencies of MR diagnostic systems and ECG monitor systems are very different. MR systems typically operate in the HF or low VHF range, below 64 MHz, whereas the ECG monitors about which HP is most concerned will use the 450-470 MHz band. NEMA members are not aware of any diagnostic magnetic resonance imaging systems that operate within the United States in this UHF band. To do so would require a DC magnetic field strength of more than 10 Tesla, which is well beyond **ANY** feasible commercial technology!

Indeed, HP sells the same ECG device on an OEM basis to many NEMA members, who incorporate the HP device, without modification, for use in monitoring the electrocardiogram of the patient during the MR test. The ECG signal so transmitted from the patient to the control console of the MR system is monitored by the operator and it is also used to sense the QRS wave form to produce a trigger to time synchronized MR data acquisition with the heart pumping action of the patient. In this case, the ECG device is in its worst-case environment, being exposed to and operational **inside** of the MR diagnostic system environment. When

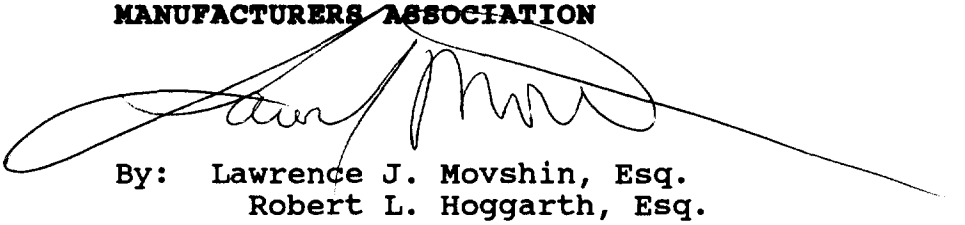
the ECG is operating outside the system's environment, it will be further shielded from the MR system's radio frequency emissions. NEMA simply does not believe that the MR environment presents any threat to the type of devices that HP manufactures. Indeed, as already noted, and as would be further demonstrated in the context of a rulemaking proceeding, NEMA members are also critically concerned for the sanctity of the hospital/medical radio-frequency noise environment. NEMA is convinced that the reduced level of record keeping and regulatory testing that would result from the requested exemption would not in any way negatively impact that sanctity.

In sum, the limited record in this proceeding confirms the need for and wisdom of initiating very quickly the proceedings necessary to provide for the requested exemption. As HP has noted, the public interest is not served by imposing burdensome regulations and record keeping requirements that will not significantly improve the potential for objectionable interference. This is particularly true where, as here, the burdens of the regulations will increase the cost of medical care, a result that can not be justified in this case. For the reasons established in the Petition, NEMA urges prompt initiation of rulemaking

proceedings designed to exempt non-consumer magnetic resonance diagnostic systems from the technical standards and the reporting requirements of Part 18 of the Commission's rules.

Respectfully Submitted,

THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION



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April 6, 1992

CERTIFICATE OF SERVICE

I, Angelia T. Torres, hereby certify that a copy of the foregoing Reply Comments of The National Electrical Manufacturers Association has been served via first-class mail, postage prepaid this 6th day of April, 1992 to the following:

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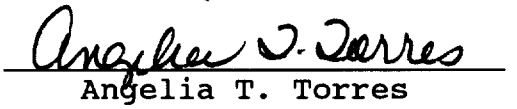

Angelia T. Torres

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